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April 18, 2024

REDACTED - PUBLIC VERSION

VIA CM/ECF

The Honorable William C. Bryson
United States Court of Appeals
Howard T. Markey National
Courts Building
717 Madison Place, N.W.
Washington, DC 20439-0000

Re: *Alcon Inc., et al. v. Padagis Israel Pharmaceuticals Ltd., et al.*, C.A. No. 22-1422-WCB

Dear Judge Bryson,

We represent Defendants Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC (collectively, “Padagis”) in the above-captioned case and write to request supplemental claim construction proceedings. As the case has proceeded into expert discovery, it has become clear that the parties dispute the meaning of a claim phrase that has not yet been construed by the Court. Specifically, Padagis requests construction of the claim phrase “comprising: a first polyol, the first polyol being selected from mannitol, sorbitol, or a combination thereof” (hereinafter, the “first polyol limitation”). The first polyol limitation appears in all asserted claims of both asserted patents, U.S. Patent Nos. 9,044,484 and 9,421,265. While many asserted claims explicitly contain a limitation on the concentration of the first polyol, some lack such an explicit limitation. See, e.g., ’265 patent, claim 1.

Based on Alcon’s opening expert reports, Padagis understands that Alcon contends that the presence of [REDACTED]

[REDACTED] in a composition is sufficient to satisfy the first polyol limitation. Padagis contends that the claim limitation requires a material or meaningful amount of [REDACTED] to be present in the composition. Because a material dispute exists between the parties regarding the scope of the first polyol limitation, Padagis requests the Court conduct supplemental claim construction proceedings to resolve this dispute.

Alcon opposes Padagis's request because it believes that Padagis has waived the ability to request construction of the first polyol limitation by not raising it during the initial claim construction proceedings¹, suggesting that Padagis should have understood the full scope of Alcon's infringement positions from Alcon's initial infringement contentions. *See* Ex. 1; Ex. 2 As an initial matter, we note that Alcon likewise did not request construction of the first polyol limitation. Moreover, Alcon's initial infringement contentions, served on April 6, 2023, did not provide Padagis with sufficient notice to understand the existence and relevance of the present claim construction dispute between the parties.

Alcon's initial infringement contentions asserted literal infringement of claims 1-3 and 6-23 of the '484 patent and claims 1-3 and 6-20 of the '265 patent. With respect to the first polyol limitation, Alcon asserted that "Padagis's ANDA Products includes a first polyol that is [REDACTED]." *See* Ex. 3 at Ex. A p.8 (contentions regarding claim 1 of the '484 patent). But [REDACTED] is not an ingredient in Padagis's ANDA Products, as evidenced by Padagis's ANDA documents. Alcon then referenced a separate Padagis product (Padagis's [REDACTED]) that contains [REDACTED] and [REDACTED]. *Id.* Alcon concluded that "[f]urther discovery is therefore expected to confirm that Padagis's ANDA Product includes [REDACTED]." *Id.* Alcon made these same contentions for the first polyol limitation of all asserted claims, regardless of whether the claim explicitly included a concentration range for the first polyol. Accordingly, Padagis understood Alcon to contend that it expected to find [REDACTED] in Padagis's ANDA product within the ranges recited in most of the asserted claims.

For claims lacking an explicit concentration limitation, such as claim 1 of the '265 patent, Alcon added only the following: "*See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338-41 (Fed. Cir. 2005) (finding infringement based on the presence of trace amounts of a component where the claim had no lower limit on the amount of the component); *see also Abbott Labs. v. Sandoz Inc.*, 566 F.3d 1282, 1299 (Fed. Cir. 2009) ('*de minimis* infringement can still be infringement')." *See id.* at Ex. B p.6. Alcon did not provide any further analysis of these case citations. Alcon's initial infringement contentions did not disclose the amount of [REDACTED] Alcon contended was purportedly present in Padagis's ANDA Products nor state that Padagis's ANDA Products purportedly contained only [REDACTED].

Alcon's final infringement contentions, served on January 25, 2024, maintained Alcon's literal infringement allegations for all asserted claims. Alcon expanded on its literal infringement theory and added an assertion that [REDACTED] but still did not disclose the amount of [REDACTED] purportedly contained in Padagis's ANDA Products. *See, e.g.,* Ex. 4 at Ex. A p.14 and Ex. B p.9. On January 31, 2024, based on Alcon's assertion in its final infringement contentions that only one ANDA batch [REDACTED] (out of three produced by Padagis) Padagis supplemented an interrogatory response seeking Padagis's non-infringement contentions to state:

¹ The parties initially disclosed claim terms for construction on May 25, 2023. The Court held a *Markman* hearing in August 2023.

“Even if some [REDACTED] were to be detected in Padagis’s ANDA Product (which Plaintiffs have not demonstrated), such a de minimis amount would not constitute infringement because ‘the term ‘comprises’ contemplates that the substance must contain more than a mere trace or de minimis amount of the named material.’ *Inforlife SA v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1740-WCB (D. Del 2023) at 10 (Bryson, J.).”

See Ex. 5 at 53.

On February 23, 2024, Alcon sent Padagis a letter characterizing the above-quoted statement as a new claim construction argument and asserting that it was purportedly too late to raise this argument. See Ex. 1 at 1-2. Padagis responded on February 27, 2024, explaining its view that it was applying the plain and ordinary meaning of the first polyol limitation in the context of the asserted patents. See Ex. 6 at 2. Alcon did not respond to Padagis’s February 27th letter.

Alcon served its opening expert reports on February 29, 2024, asserting that all asserted claims are literally infringed. Alcon’s expert reports presented several new positions not previously disclosed in its infringement contentions. For example, Alcon’s expert, Dr. Steven Little, Ph.D, took the following position with respect to the construction of the first polyol limitation:

“I understand that ‘comprising is a term of art used in patent claims to mean that the named elements are required, but other elements may be included. Unlike other claims in the ’265 patent, claim 1 does not require the composition comprise any specific concentration of the first polyol. I understand this limitation is therefore satisfied by the presence of any residual amount of a first polyol in the composition.”

Ex. 7 at ¶ 86. Dr. Little also offered an inherent infringement argument not present in Alcon’s infringement contentions, opining that “it is not thermodynamically feasible to eliminate absolutely all of an ingredient if a choice is made to expose the manufacturing equipment to that ingredient in a previous process. . . . For the reasons stated above, there will necessarily be some amount of carry-over of the [REDACTED]

Id. at ¶¶ 91-92.

Accordingly, even when Alcon’s testing did not detect any [REDACTED] in several samples of Padagis’s ANDA product, Dr. Little opined that “the most logical conclusion is that these other samples [REDACTED] *Id.* at 103.

Alcon also served an expert report from Dr. Dwight Stoll, Ph.D., who conducted testing on samples of Padagis’s ANDA Products and purported to detect [REDACTED] in one sample in an amount of [REDACTED] with a purported 95% confidence interval of [REDACTED] See Ex. 8 at ¶ 43. Dr. Stoll also purported to detect [REDACTED] in a second sample in some [REDACTED]

██████ See *id.* at ¶¶ 44-45. Dr. Stoll did not detect ██████ in any other samples of Padagis's ANDA Product.²

In view of Alcon's expert reports, which assert that amounts of ██████, literally infringe all asserted claims, Padagis notified Alcon on April 2, 2024 that it believed supplemental claim construction proceedings were needed for the first polyol limitation. Ex. 9. In a letter dated April 9, 2024, Alcon reiterated its position that Padagis had waived the ability to seek construction of the first polyol limitation. See Ex. 2. Padagis responded to Alcon's waiver arguments in a letter dated April 10, 2024. Ex. 10. The parties conducted a meet and confer on April 12, 2024, but did not reach any agreement.

In view of the foregoing, Padagis respectfully requests that the Court order supplemental claim construction proceedings to address the meaning of the first polyol limitation. Padagis believes that limited briefing for this single claim limitation and a hearing (if helpful to the Court) can be conducted within the current case schedule. Padagis proposes the following schedule:

Simultaneous opening briefs (7 page limit)	May 15, 2024
Simultaneous responsive briefs (4 page limit)	May 29, 2024
Hearing	June 2024 (at the Court's convenience)

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

cc: All Counsel of Record (via CM/ECF & email)

² Padagis produced, and Dr. Stoll tested, two bottles of Padagis's ANDA Product from each of three exhibit batches. Dr. Stoll purported to detect ██████ in certain samples from one bottle of two separate exhibit batches, but not the second bottle from those same batches. Dr. Stoll also did not detect ██████ in either bottle of the third exhibit batch.

EXHIBIT 1

ALLEN & OVERY

VIA EMAIL

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February 23, 2024

Alcon Inc. et al. v. Padagis Israel Pharmaceuticals Ltd. et al., C.A. No. 22-1422-WCB (D. Del.)

Dear Counsel,

We write on behalf of Plaintiffs Alcon Inc., Alcon Vision, LLC, and Alcon Laboratories, Inc. (“Alcon”) in the above-captioned matter to object to Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC’s (“Padagis’s”) inclusion of new claim constructions in its Final Invalidity Contentions, served on January 25, 2024, and its Supplemental Response to Alcon’s First Set of Interrogatories (No. 4), served on January 31, 2024.

As Padagis knows, the Court issued its Claim Construction Order (D.I. 78) on September 8, 2023, after extensive briefing and a Markman hearing. The order resolved several disputed terms and adopted several of Alcon’s and Padagis’s proposed positions. The Order was clear, and neither party sought reconsideration. Nonetheless, in Padagis’s Invalidity Contentions and Interrogatory Responses, which expressly acknowledge the Court’s constructions (*see* Padagis’s Second Invalidity Contentions at 5-6), Padagis raised new claim construction arguments that directly contradict the Court’s Order or introduce new issues it never presented to the Court.

First, Padagis now argues that the term “as an anti-microbial preservative” in claims 1, 13, and 20 of U.S. Patent 9,142,265 (“the ’265 patent”) should be read as a functional limitation that requires the claimed compositions to satisfy Ph. Eur. A, Ph. Eur. B, or both standards. Padagis’s Second Invalidity Contentions at 136-37. The Court’s Claim Construction Order expressly precludes Padagis’s new position by construing “preservatives” to mean “substances such as BAC, hydrogen peroxide, and polymeric quaternary ammonium compounds, which prevent the proliferation of microbes in a composition” and to exclude “substances such as borate or polyols, which merely enhance the anti-microbial effect of a preservative.” D.I. 78 at 7. At no time during the parties’ extensive exchanges on claim construction did Padagis ever raise the new construction that it now proposes. To the contrary, Padagis insisted that the term was indefinite. *See, e.g.*, D.I. 64 at 5-10.

Second, Padagis now raises a new argument regarding a claim term that was never at issue between the parties and that would require, at a minimum, additional expert discovery. Specifically, in Padagis’s Supplemental Response to Interrogatory 4, it now argues that “the term ‘comprises’ contemplates that the substance must contain more than a mere trace or de minimis amount of the named material” and that Padagis’s ANDA Product cannot

therefore meet the limitation of claim 1 of the '265 patent requiring a first polyol. Padagis's Supplemental Response to Interrogatory 4 at 53. Again, Padagis's new claim construction argument is too late. Padagis has been on notice of Alcon's position that Padagis's ANDA Product contains [REDACTED] since at least April 6, 2023, when Alcon served its Initial Infringement Contentions, and well in advance of Padagis's Initial Claim Construction Disclosure served on May 25, 2023, Padagis's Responsive Claim Construction Brief (D.I. 64) filed on July 24, 2023, and Padagis's Sur-Reply Claim Construction Brief, filed on August 11, 2023 (D.I. 71). Padagis had ample opportunity to raise this term with the Court during claim construction but failed to do so, and is now precluded from raising these new arguments. *See Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 640-41 (Fed. Cir. 2011) (finding the district court did not abuse its discretion by refusing to hear new claim construction theories a year after the court's *Markman* order). Nothing about Alcon's positions has changed that warrants Padagis's new-found argument.

Padagis's inclusion of these new claim construction arguments in its invalidity contentions and interrogatory responses is a clear attempt to circumvent the Court's Order and to inject new theories of invalidity and non-infringement into this case. This is not only contrary to the rules of civil procedure, the local patent rules, and the Judge's Scheduling Order (D.I. 19), but also to the principles of fairness and judicial efficiency. *See, e.g., MercAsia USA Ltd. v. Zhu*, No. 3:17-cv-718 JD, 2023 WL 1991701, at *10 (N.D. Ind. Feb. 14, 2023) (finding that "ongoing claim construction to assist the nine new contentions would greatly prejudice" the plaintiff by elongating the case and "setting the parties back unnecessarily"). Padagis's new arguments prejudice Alcon by requiring Alcon's experts to address more than one claim construction, including those that Padagis failed to raise during the extensive claim construction process that the Court put in place in this litigation. In addition to creating uncertainty and confusion about the scope and meaning of the claims, Alcon was unable to explore Padagis's eleventh-hour constructions during fact discovery. Alcon was precluded from exploring Padagis's positions through document discovery, written discovery, and during the depositions of Padagis's witnesses. Absent reopening fact discovery, that prejudice cannot be cured. *See Galderma Labs., LP v. Amneal Pharm. LLC*, C.A. No. 16-0207-LPS, D.I. 203 (D. Del. Nov. 29, 2017) (granting motion to strike supplemental contentions which asserted a new theory for the first time after discovery ended); *Greatbatch Ltd. v. AVX Corp.*, C.A. No. 13-723-LPS, D.I. 381 (D. Del. Aug. 17, 2015) (striking new contentions because they were materially different and inconsistent with prior contentions, and because under the *Pennypack* factors, there was no way to avoid prejudice without reopening discovery and causing "dramatic change to the case schedule").

Alcon requests that Padagis withdraw the new claim construction arguments in its invalidity contentions and interrogatory responses and confirm that Padagis will adhere to the Court's Claim Construction Order for the remainder of this case. If Padagis fails to do so, Alcon will seek appropriate relief from the court, including, without limitation, moving to strike any expert opinions based on Padagis's new theories and/or challenging the admissibility and relevance of any evidence or testimony that is based on Padagis's new arguments.

Regards,

/s/ Michelle Bone

Michelle Bone

Associate

EXHIBIT 2

ALLEN & OVERY

VIA EMAIL

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April 9, 2024

Alcon Inc. et al. v. Padagis Israel Pharmaceuticals Ltd. et al., C.A. No. 22-1422-WCB (D. Del.)

Counsel,

Alcon does not believe that there is a claim construction dispute to bring to the Court's attention, nor did it express such a belief in its letter dated February 23, 2024. Rather, in its February 23rd letter, Alcon stated that Padagis's attempt to argue a new construction for a term that was never at issue during claim construction was too late.

Alcon has always made clear to Padagis that a de minimis amount of [REDACTED] both falls within the scope of the claims and infringes the claims. Alcon's Initial Infringement Contentions, served a year ago, on April 6, 2023, pointed to the fact that [REDACTED]

[REDACTED] See Initial Infringement Contentions Ex. B at 5; *id.* at 6 (citing *Abbot Labs. v. Sandoz Inc.*, 566 F.3d 1282, 1299 (Fed. Cir. 2009)) ("de minimis infringement can still be infringement."); *id.* at 6 (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338-41 (Fed. Cir. 2005)) ("finding infringement based on the presence of trace amounts of a component where claim had no lower limit on the amount of the component"). Alcon expressed the same view in its Final Infringement Contentions, served on January 25, 2024. See Final Infringement Contentions Ex. B at 8 ("[REDACTED]"); *id.* at 9 (citing *SmithKline Beecham*, 403 F.3d 1131) (citing *Abbott*, 566 F.3d 1282).

Despite Padagis's knowledge of Alcon's positions, Padagis waited until its supplemental interrogatory response on January 31, 2024, to begin to advance its new claim construction theory. And after Alcon pointed out that Padagis's new claim construction was untimely on February 23, 2024, Padagis insisted it was not offering a new claim construction and no dispute existed in its February 27, 2024, response. Padagis now contends that it was unable to evaluate whether there was a claim construction dispute without Alcon's expert reports, but Padagis's own expert report served on February 29, 2024, demonstrates that Padagis and its expert were aware of and understood Alcon's infringement positions prior to receiving Alcon's opening expert reports. See, e.g., Dyar Report at Para. 693 ("I understand that Plaintiffs have taken the position that even very small amounts of [REDACTED] could infringe the 'first polyol' limitation."). Even then Padagis waited more than a month to raise its newly hatched "dispute." But there is no ripe claim construction dispute, Alcon's position has not changed, and Padagis long ago waived its opportunity to raise claim construction arguments.

Padagis's untimely claim construction arguments prejudice Alcon, which has now already served its opening expert reports on infringement. Adoption of Padagis's construction would require, at minimum, supplemental expert reports on infringement to address the construction and a modification of the case schedule to accommodate supplemental reports. As Padagis is well aware, trial is scheduled to begin in less than six months, and a change in the construction of a claim term at this late stage of the case would also necessitate delaying trial.

Furthermore, Padagis's assertions about the scope of the claims being altered are specious. Nothing about Alcon's position "fundamentally changes the scope of the claims." Alcon does not assert that a composition that is free of a first polyol would infringe claim 1 of the '265 patent. Rather, the claim construction position that Padagis first asserted on January 31, 2024, in its Supplemental Response to Interrogatory 4, that "the term 'comprises' contemplates that the substance must contain more than a mere trace or de minimis amount of the named material" reads an additional limitation into the claim, is unsupported by law and the intrinsic evidence, and has never been the plain and ordinary meaning of "comprises." In fact, Padagis's position directly controverts established Federal Circuit law. See *SmithKline Beecham*, 403 F.3d at 1339-40 (finding the district court erroneously read in a limitation for "commercially significant amounts" of a compound); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1344-45 (Fed. Cir. 2003) ("Comprising is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); see also *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998) ("'Comprising' is not a weasel word with which to abrogate claim limitations.").

Contrary to your assertion, Alcon's understanding of the claims does not lead to a "bizarre situation" from a policy perspective – it is a straightforward application of accepted Federal Circuit precedent. *Abbot Labs. v. Sandoz Inc.*, 566 F.3d at 1299 ("de minimis infringement can still be infringement."). And even if a policy issue existed, it would have no bearing on the meaning of "comprising." Such a policy-based view of claim construction has been expressly rejected by the Federal Circuit. *SmithKline Beecham*, 403 F.3d at 1339 ("Claim construction, however, is not a policy-driven inquiry."); *id.* ("The scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning."). Padagis cites nothing supporting its implausible construction under the facts presented here.

Alcon disagrees that the Court needs to be notified of a claim construction dispute at this time. Padagis's positions are unsupported and Padagis has waived its new claim construction arguments by failing to timely raise them. As previously indicated in our February 23, 2024, letter, Alcon will seek all appropriate relief from the Court, including, without limitation, moving to strike any arguments or expert opinions relying on Padagis's untimely claim construction.

Regards,

/s/ Michelle Bone

Michelle Bone

Associate

**EXHIBITS 3-5
REDACTED IN
ENTIRETY**

EXHIBIT 6

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Andrea Cheek
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February 27, 2024

VIA EMAIL

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Re: *Alcon Inc. et al. v. Padagis Israel Pharmaceuticals Ltd. et al.*, C.A. No. 22-cv-1422-WCB (D. Del.)

Dear Counsel:

We write on behalf of Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC's ("Padagis") in response to Alcon Vision, LLC, and Alcon Laboratories, Inc. ("Alcon's") February 23, 2024 letter in the above-captioned matter.

Padagis disagrees with Alcon's erroneous assertions in its February 23, 2024 letter. Padagis has not raised any new claim construction arguments, nor has Padagis presented any late disclosures. We were particularly surprised to see Alcon (incorrectly) complaining about late disclosures since it is Alcon, not Padagis, who engaged in dilatory tactics.

Claims 1, 13 and 20 of U.S. Patent 9,142,265 ("the '265 patent") – Preservative Limitation

First, Alcon asserts that Padagis newly argues that the term "BAC as an anti-microbial preservative" in claims 1, 13, and 20 of the '265 patent is a functional limitation. The same term appears in the 9,044,484 patent ('484 patent) claims. Padagis' invalidity contentions explained that the '265 patent claims include very low BAC concentrations without any evidence that BAC could act as an anti-microbial preservative at those levels. Padagis also explained that '265 claim 1, as evidenced by dependent claim 2, necessarily includes within its scope compositions that satisfy the Ph. Eur A and/or B standards. Yet the patent itself suggests even BAC concentrations much higher than those included in the claimed scope will not meet the Ph. Eur A and/or B standards without sufficient concentrations of polyols and borate. Padagis' Second Invalidity Contentions at 138.

During claim construction, both Alcon's and Padagis's proposed constructions of the preservative limitation recognized the functional aspect of "as an anti-microbial preservative." The Court likewise construed "preservatives" as substances that "prevent the proliferation of microbes in a composition." D.I. 78 at 7. Padagis applied the Court's construction, including the functional requirement that a preservative prevents the proliferation of microbes in the composition. Applying the Court's construction is the opposite of taking a new claim construction position.

Indeed, Alcon has repeatedly taken the position that “preservative” is a functional limitation. For example, Alcon (incorrectly) argues that preservative efficacy distinguishes the prior art from the claims: “Padagis has not explained why a POSA would have reasonably expected, based on the disclosures in the prior art, a composition having a BAC concentration with the claimed range **would have sufficient preservative efficacy** to be suitable as a multi-dose ophthalmic composition.” Alcon’s Supplemental Objections and Responses to Padagis’ First Set of Interrogatories (Nos. 1-15) at 62, 66, 69, 73 (emphasis added).

Alcon further states that “a skilled artisan reading Chowhan would have no reasonable expectation of success in developing a composition having ingredients at the concentrations claimed in the Patents-in-Suit.” *Id.* at 63. Later Alcon argues: “a skilled artisan reading the Alphagan® Product Insert would have no reasonable expectation of success in developing a composition having ingredients at the concentrations claimed in the Patents-in-Suit.” *Id.* at 67. And yet again Alcon asserts: “a skilled artisan reading the Azopt® Product Insert would have no reasonable expectation of success in developing a composition having ingredients at the concentrations claimed in the Patents-in-Suit.” *Id.* at 68. Alcon is clearly implying a functional and preservative efficacy requirement. Alcon is not suggesting that a POSA would not be able to mix the ingredients at the claimed concentrations together to make a composition.

Alcon also relied on the functional requirement of BAC as a preservative during prosecution. *Id.* at 76. For example, Alcon argued that an ordinarily skilled artisan expected that lowering the BAC concentration would have resulted in failure of European and even U.S. pharmacopeia preservation standards, and that it is unexpected that the compositions of the claims exhibit such robust preservation at such low concentrations of BAC. *Id.* Thus, Alcon’s unexpected results similarly interpret the preservative limitation as functional.

If Alcon maintains its new position that the preservative limitation is not functional, please confirm that Alcon is withdrawing all validity arguments relying on the function of the claimed compositions as inconsistent with the court’s construction.

Claim 1 of the ’265 patent – Comprises

Second, Alcon erroneously alleges that Padagis raises a new argument that “the term ‘comprises’ contemplates that the substance must contain more than a mere trace or de minimis amount of the named material.” This is not a new argument, just the plain and ordinary meaning of the term in the context of the asserted patents.

Regardless, any such argument is hardly belated. Padagis updated its non-infringement interrogatory response soon after receiving Alcon’s final infringement contentions. *See* Padagis’ Objections and Responses to Plaintiff’s Third Set of Interrogatories (Nos. 13-14) at 3-4. Padagis provided its first interrogatory response on February 23, 2023, well before Alcon had provided its contentions on April 6, 2023, and Alcon never requested that Padagis supplement its response. (*See* Padagis’ Objections and Responses to Plaintiff’s First Set of Interrogatories; *See* Plaintiffs’ Initial Infringement Contentions.) There is nothing belated about Padagis providing non-infringement positions in a supplemental interrogatory response during fact discovery.

Alcon further argues that the “comprising” term is either a claim construction (legal) issue or an expert issue (where discovery is ongoing). Alcon is not prejudiced by any alleged lack of fact discovery and does not even identify any fact discovery that they would have sought but could not. Moreover, Alcon

has repeatedly expressed the view that depositions needed to be completed prior to providing final contentions in this case and sought modifications to the case schedule on several occasions. Alcon cannot now suggest that it is prejudiced by receiving contentions or interrogatory responses to those contentions near the close of fact discovery, after the completion of depositions.

Further, Alcon's position is particularly meritless because Alcon has never provided any disclosure regarding the amount of [REDACTED] Alcon contends is present in Padagis' ANDA product. Padagis reserves all rights to respond fully to any presently undisclosed contentions by Alcon or its experts regarding the purported amount of [REDACTED] present in Padagis's ANDA product.

Alcon's Late Disclosures

Alcon waited until the last day of fact discovery to provide any contentions and factual support with respect to commercial success. *Compare* Original Response to Interrogatory No. 14 with Feb. 1 Supplemental Response to Interrogatory No. 14. Alcon's failure to provide any information regarding its commercial success arguments is particularly prejudicial to Padagis as the information Alcon relies upon was within its control and at least available as of the date of Padagis's Interrogatory No. 14 was served. Because Alcon waited until the last day of discovery, and after all depositions were complete, to provide any commercial success argument, Padagis was unable to probe any of Alcon's contentions with Alcon's witnesses (witnesses Alcon now relies upon to support its commercial success contentions).

As described above, Padagis has and will continue to adhere to the Court's Claim Construction Order. As noted in related correspondence, Alcon's continued assertion of a claim that the Court found to be invalid in its Claim Construction Order, is in fact circumventing the Court's Order and Padagis reserves its rights as noted in that correspondence.

Sincerely,

/Andrea Cheek/

Andrea Cheek

cc: Counsel of Record

EXHIBIT 7
REDACTED
IN
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EXHIBIT 8
REDACTED IN
ENTIRETY

EXHIBIT 9

Andrea Cheek

From: Andrea Cheek
Sent: Tuesday, April 2, 2024 4:23 PM
To: Simbrinza Litigation; SKAlconSimbrinza@shawkeller.com
Cc: Knobbe.brimbrinz; Jack Phillips; Megan C. Haney
Subject: C.A. No. 22-1422-WCB Alcon, Inc., et. al. v. Padagis Israel Pharmaceuticals Ltd., et. al. | Supplemental Claim Construction

Counsel:

In a letter dated February 23, 2024, you indicated that you believed there was a possible new claim construction dispute as to the meaning of comprising a first polyol. On February 27, 2024 we sent a responsive letter. We explained, among other things, that the plain and ordinary meaning of the term “comprises,” in the context of the patents and claims, is more than a trace or de minimis amount of the named compound. Feb. 27 Letter at 2. We further explained “Alcon has never provided any disclosure regarding the amount of [REDACTED] Alcon contends is present in Padagis’ ANDA product” and that we reserved “all rights to respond fully to any presently undisclosed contentions by Alcon or its experts.” Feb. 27 Letter at 3.

Since we did not yet have your expert reports or your full theory of infringement, we did not have enough information to determine whether there was a ripe claim construction dispute. Now, we do. It appears that your infringement position, articulated through your experts, is that [REDACTED] [REDACTED] fall within the scope of the claims. We disagree with this understanding since it fundamentally changes the scope of the claims, particularly ’265 claim 1, from a composition comprising a first polyol to a composition “free or substantially free” of a first polyol. It also creates the bizarre situation where entirely new equipment must be purchased for every single product due to the risk of what you view as the inevitable infringement by a [REDACTED]. That is not how either the patents or the art uses the term “comprising” a substance.

We also disagree with you on the factual basis for your infringement theories, as we previously indicated in our interrogatory responses and as will be further set forth by our experts. But, since there is a ripe claim construction dispute, and irrespective of your specious factual assertions, we think the next step is to notify the Court that dispositive motions will likely require resolution of the disputed claim term. Please let us know when you are available for a meet and confer on this issue.

Regards,
Andrea

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EXHIBIT 10

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Andrea Cheek
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VIA EMAIL

April 10, 2024

Michelle Bone
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Re: *Alcon Inc. et al. v. Padagis Israel Pharmaceuticals Ltd. et al.*, C.A. No. 22-cv-1422-WCB (D. Del.)

Dear Michelle:

We write in response to your April 9th letter. We disagree with many of your assertions, but what is clear is that the parties have a live and material dispute regarding the meaning of the claim limitation “comprising: a first polyol, the first polyol being selected from mannitol, sorbitol, or a combination thereof” (hereinafter “the first polyol limitation”).

Alcon’s initial infringement contentions, served April 6, 2023, did not sufficiently put Padagis on notice of the present claim construction dispute. Alcon’s contentions stated that “Padagis’s ANDA Product includes [REDACTED] as a first polyol” and “Further discovery is therefore expected to confirm that Padagis’s ANDA Product includes [REDACTED]”

[REDACTED] Alcon’s Initial Infringement Contentions, Ex. B at 5-6. While Alcon cited *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005) and *Abbott Labs v. Sandoz Inc.*, 566 F.3d 1282 (Fed. Cir. 2009), Alcon did not explicitly disclose its contention that amounts of [REDACTED] would allegedly satisfy the first polyol limitation. Nor did Alcon disclose a theory of inherent infringement by even a [REDACTED]

[REDACTED] Little Report ¶91. The fact that Alcon offered the same statements in its initial infringement contentions for literal infringement of, e.g., claim 1 of the ’484 patent, which requires “a first polyol, the first polyol being selected from mannitol, sorbitol, or a combination thereof **wherein the concentration of the first polyol in the composition is at least 0.15 w/v % but is less than 0.5 w/v%**,” further compounded the lack of clarity regarding Alcon’s contentions, suggesting that Alcon expected to find an amount of [REDACTED] in Padagis’s ANDA product that would meet the concentration limitation of claim 1 of the ’484 patent. *See id.* at Ex. A at 7-9

In Alcon’s final infringement contentions, served January 25, 2024, Alcon added a contention that

[REDACTED] and [REDACTED] *See, e.g.,* Alcon’s Final Infringement Contentions, Ex. B at 5-8. Alcon chose, however, not to disclose the testing results or the amount of

██████████ purportedly present in Padagis's product. And again, Alcon offered these same contentions for, e.g., both claim 1 of the '265 patent and claim 1 of the '484 patent, further compounding the lack of clarity regarding the amount of ██████████ Alcon would contend was present in Padagis's product.

Because Alcon's final infringement contentions alluded to the possibility that Alcon may assert that ██████████ was present in only one of Padagis's exhibit batches (for example by citing only one of three exhibit batches as purportedly ██████████), Padagis suspected, but did not have confirmation, that Alcon may contend that trace amounts of mannitol were sufficient to establish infringement of all asserted claims. Accordingly, Padagis served a supplemental response to Alcon's Interrogatory No. 4¹ on January 31, 2024 stating, *inter alia*:

- Even if some trace amount of ██████████ were to be detected in Padagis's ANDA Product (which Plaintiffs have not demonstrated), such a de minimis amount would not constitute infringement because "the term 'comprises' contemplates that the substance must contain more than a mere trace or de minimis amount of the named material." *Inforlife SA v. Sun Pharm Indus. Ltd.*, C.A. No. 21-1740-WCB (D. Del. 2023) at 10 (Bryson, J.).
- There is no evidence that any ██████████ is present in any meaningful or material amount.
- Accordingly, and for the reasons previously set forth, Plaintiffs cannot establish literal infringement of claim 1 [of the '265 patent].

Padagis's Supplemental Responses to Alcon's First Set of Interrogatories (No. 4) at 53 (bullets added).

In your letter dated February 23, 2023, you accused Padagis of contradicting the Court's claim construction order or introducing new issues. Feb. 23 Letter at 1. In particular, you took the position that Padagis's supplemental interrogatory response stating that "the term 'comprises' contemplates that the substance must contain more than a mere trace or de minimis amount of the named material" was a new claim construction argument. *Id.* at 2. In our responsive letter dated February 27, 2023, we explained that in our view, we were not raising a new claim construction argument, but merely applying the plain and ordinary meaning of the term "comprises" in the context of the asserted patents. Feb. 27 Letter at 2. Alcon did not respond to Padagis's letter.

As explained in our email dated April 2, 2024, Alcon's opening expert reports confirmed that the parties have different understandings of the plain meaning of "comprises" and the first polyol limitation. Alcon's position that Padagis should have comprehended from Alcon's initial infringement contentions that Alcon would eventually advance a literal infringement theory based on the purported presence of ██████████ such that Padagis waived the ability to seek construction of the first polyol limitation is unsupported by the facts or the case law. To the contrary, "[t]he court has a duty to resolve fundamental disputes about the meaning of claims even when the disputes arise after claim construction proceedings are concluded." *Prolitec Inc. v. ScentAir Techs., LLC*, 2023 WL 8697973 at *5 (D. Del. Dec. 13, 2023) (resolving a claim construction dispute that arose during summary judgment proceedings); *see also O2 Micro Int'l, Ltd. v. Beyond innovation Tech. Co.*, 521 F.3d 1351 (Fed. Cir. 2008) ("In this case, the 'ordinary' meaning of a term does not resolve the parties' dispute, and claim construction requires the

¹ Padagis timely served its initial response to Alcon's interrogatories on February 23, 2023, well before Alcon served its initial infringement contentions.

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Michelle Bone
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court to determine what claim scope is appropriate in the context of the patents-in-suit.”). Accordingly, Padagis intends to request that the Court resolve the dispute.

We also need to raise another legal issue that we hope will simplify the case. After reviewing Alcon’s expert reports it is now clear that Alcon’s infringement theories rely on an incorrect understanding of the law articulated in *Sunovion*, which you cited in your contentions. Your expert takes the position that

[REDACTED] As you undoubtedly know, the Federal Circuit rejected this interpretation of *Sunovion*. Instead, the Federal Circuit explained that *Sunovion* only applies when the “ANDA specification defines a compound such that it meets the limitations of an asserted claim.” *Ferring v. Barr Labs.*, 764 F.3d 1382, 1387 (Fed. Cir. 2014) (cleaned up). When an “ANDA is silent with respect to the claim limitations of the patents-in-suit,” as is the case here with respect to the [REDACTED], *Sunovion* does not apply. *Id.* at 1387-88. In that situation, batch data demonstrating what the ANDA applicant is “likely to sell”—not the silent ANDA—is relevant to the infringement inquiry. *Id.* at 1388. Indeed, the Federal Circuit rejected the idea that “the alleged infringer must disprove infringement if the ANDA permits sale of a composition that may include an infringing product.” *Id.* (cleaned up). That is the premise you and your expert depend on for establishing literal infringement of nearly all asserted claims.

There is no dispute that Padagis’s ANDA product does not have even [REDACTED]. Since a legally erroneous understanding is not a valid basis for infringement, we believe the best next step is that you stipulate to no literal infringement for all claims that include a [REDACTED]. Among other things, that will help simplify the issues for the Court and allow the parties to focus on the actual disputes. We, of course, reserve all rights with respect to your pursuit of what you must know is a legally erroneous and factually unsupported theory of infringement.

Please provide your availability to meet and confer on April 11th or 12th.

Sincerely,

/Andrea Cheek/

Andrea Cheek

cc: Counsel of Record